

MAR 29 2013

Submission Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	November 5, 2012
Establishment Registration No.	1528028
Trade/Proprietary Name:	SCENARIO Phase 2 Whole-body X-ray CT System
Classification Name:	Computed Tomography X-ray System
Product Code	JAK
C.F.R. Section:	892.1750
Regulatory Class	Class II
Predicate Device(s):	SCENARIO Whole-body X-ray CT System (K101888)
Reason for Submission	New Technology

Device Intended Use

The SCENARIO Phase 2 system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, gated or dynamic modes.

The volume datasets acquired by the SCENARIO Phase 2 can be post processed by the SCENARIO Phase 2 to provide additional information. Post processing capabilities included in the SCENARIO Phase 2 software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.

Volume datasets acquired by the SCENARIO Phase 2 can be transferred to external devices via a DICOM standard interface.

The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

Function

The SCENARIO Phase 2 is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles.

Scientific Concepts

The SCENARIA Phase 2 system uses 64-slice CT technology, where the X-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 64 slices of data simultaneously. The X-ray sub-system features a high frequency generator, X-ray tube, and collimation system that produces a fan beam X-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the X-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a Computer Workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The SCENARIA Phase 2 system consists of a Gantry, Operator's Workstation, Patient Table, high-Frequency X-ray Generator, and accessories. The system performance is similar to the predicate device.

Performance Comparison

A clinical evaluation comparison was conducted with the SCENARIA Phase 2 system and the original SCENARIA System (K101888) and found to be substantially equivalent as documented in Section 12 – Performance Testing – Clinical.

In addition, evaluations were conducted for dose profile, image noise, Modulation Transfer Function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index as documented in Section 11 – Performance Testing – Bench.

The evaluation results confirm the performance characteristics of the SCENARIA Phase 2 are comparable to the predicate device and support our conclusion that the SCENARIA Phase 2 system is substantially equivalent.

Device Technological Characteristics

The SCENARIA PHASE 2's Gantry, X-ray Tube, X-ray Generator, and Patient Table specifications are the same as the SCENARIA System (K101888). Likewise, the Helical Scanning, Image Processing, Display, Image Storage, and Performance features are equivalent to the predicate device. Lastly, the features related to dose which are available on the predicate device are also included on the SCENARIA PHASE 2. See Section 4 – Comparison to Predicate Device for additional information.

Therefore, the SCENARIA Phase 2 system is technologically equivalent in concept, function, and performance to the predicate device.

Safety and Effectiveness

The SCENARIA Phase 2 is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820.

Additionally this system is in conformance with the applicable parts of:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-1:2000 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))
- IEC 60601-1-3: 1994 Edition 1.0, Medical electrical equipment - Part 1-3 - Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment.
- IEC 60601-2-32: 1994 Edition 1.0, Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-44 (2002-11) Edition 2.1, Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

Conclusions

The SCENARIA Phase 2 system has been developed and validated according to applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 29, 2013

Hitachi Medical Systems America, Inc.
% Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K123509

Trade/Device Name: SCENARIA Phase 2 Whole-body X-ray CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 25, 2013
Received: February 26, 2013

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123509

Device Name: **HITACHI SCENARIO Phase 2 Whole-body X-ray CT System**

Indications for Use:

The SCENARIO Phase 2 system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, gated or dynamic modes.

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123509